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EXAMINER
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LIU, SUE XU

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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10/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/056,734

Applicant(s)

SPITZER, A. ROBERT

Examiner

Sue Liu

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-21, 28, 29, 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/07 has been entered.

### ***Claim Status***

2. Claims 23-27 have been cancelled.

Claims 1-22 and 28-32 are currently pending.

Claims 1-21, 28, 29, 31 and 32 have been withdrawn.

Claims 22 and 30 are being examined in this application.

### ***Election/Restrictions***

3. Applicant elected without traverse to prosecute the invention of group II, claims 22, 25, 27, and 30, as acknowledged in the previous Office action mailed 4/11/05 at p. 3, para 6.

### ***Priority***

4. This application claims benefit of provisional application 60/264,413 filed on 01/26/2001, and provisional application 60/302,799 filed on 7/3/2001.

Art Unit: 1639

***Claim Objections / Rejections Withdrawn***

5. In light of applicant's amendments to the claims, the following rejection to the claims as set forth in the previous office action is withdrawn:

Claims 22 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. However, new issues under 35 USC 112, 2<sup>nd</sup> paragraph arise for claim 22 due to applicant's amendment to the claim. See the 112 2<sup>nd</sup> rejection under the section "New Claim Objections/Rejections" in the instant office action.

***Claim Objections / Rejections Maintained***

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Hoogdalem and Raskin***

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Hoogdalem et al (Clin. Pharmacokinet. Vol. 21 (1): 11-26; 1991; cited previously), in view of Raskin (The Western Journal of Medicine. Vol. 161: 299-302; 1994; cited previously). The previous rejection

Art Unit: 1639

is maintained for the reasons of record as set forth in the Office action, mailed 10/2/06, at p. 13+, as well as the discussion below.

Discussion and Answer to Argument

8. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicant argues there is no motivation to combine the references. (Reply, p.8, para 1).*

Applicant is respectively directed to the previous Office action (mailed 10/2/06; p.14; especially para 1 and 3) for discussion of motivation to combine.

In addition, applicants are also respectively directed to the recent Supreme Court decision, which forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. *KSR, 127 S.Ct. at 1741, 82 USPQ2d at 1396.*

As discussed previously, Van Hoogdalem et al, throughout the reference, teach rectal drug administration of various drug formulations such as valproate suppository (Summary and p. 19-20).

The Raskin reference teaches using valproate sodium for treatment of migraine (see Table 1 of the reference). The reference also teaches valproate sodium "appears to be remarkably effective" in treating migraine (p. 302, para 3). The reference further teaches rectal suppository formulation used for migraine treating medications and rectal administration through suppository is a routine method of administering migraine medications (e.g. Abstract; p.299, right col., para 2).

A person of ordinary skill in the art would have been motivated at the time of the invention to use valproate in the form of a suppository to treat migraine, because valproate, sodium valproate or valproate salts is shown to be effective in treating migraine and offers the advantage for their "remarkable" effectiveness for treating migraine.

Because both of the Hoogdalem and Raskin references teach administering valproate compounds either in an oral form or a rectal suppository form for treatment of diseases such as epilepsy or migraine, it would have been obvious to one skilled in the art to substitute one method of oral administering valproate compounds for a rectal suppository method to achieve the predictable result of treating migraine.

*Applicant also asserts "there is not any data available in the prior art that valproate sodium is effective in suppository form as a treatment for migraines" (Reply. p.8, para 1).*

Applicant has made the above statement in contrary to the presented evidence of record. As discussed above, the Hoogdalem reference teaches successful administration of a suppository comprising valproate for effective treatment of a disease, and the Raskin reference teaches successful administering valproate for effective treatment of migraine. The Raskin reference also teaches rectal administration (i.e. through a suppository) is known to be an effective drug delivery method especially for migraine treatment. Thus, all the cited references suggest a suppository of valproate would be effective in treating migraine.

In addition, obviousness does not require absolute predictability. In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); In re Clinton, 527 F.2d 1226, 188 USPQ 365 (CCPA 1976).

Art Unit: 1639

Sorensen and Murata

9. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorensen (Acta Neurologica Scandinavica. Vol. 78: 346-348; 1988; cited previously), in view of Murata (US 5,500,221; 3/19/1996; cited in the previous Office action, mailed 2/21/06). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 10/2/06, at p. 14+, as well as the discussion below.

Discussion and Answer to Argument

10. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicant states "applicant has amended claim 30 to have closed language as suggested by the Office action". (Reply, p.10, para 1).*

The previous office action (mailed 3/23/07; pp.5-6) has pointed out that the "consisting essentially of" language (used in applicant's argument) was not recited in the instant claims (claims as filed on 12/29/06), and did not state that the transition phrase "consisting essentially of" is closed language.

Applicants are respectively directed to MPEP 2111.03 for guidance on interpretation of various transition phrases:

"The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original)...

"A consisting essentially of" claim occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54

Art Unit: 1639

(Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003)..."

"*In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)"

(emphasis added).

In the instant case, applicant has not provided any evidence to indicate that the transition phrase "consisting essentially of" should be interpreted as closed language. The instant specification, on the other hand, does indicate that the phrase "consisting essentially of" should be interpreted to mean open language. That is the "additional components" would not materially change the characteristics of applicant's invention, as according to the case law.

The instant specification does not disclose "a suppository" that "consist of" only valproate, sodium valproate, or valproate salts. The instant specification discloses "medication composition" that "includes" various chemical compounds such as the ones listed at p. 5, lines 12+. The instant specification also discloses that the "medication composition" would comprise other ingredients so that the medication composition can be in various forms such as liquid, gel, paste, suspension, etc., as disclosed at p. 5, lines 22. The instant specification also discloses that the medication composition can include other substances such as thickeners, pharmaceutical



Art Unit: 1639

carriers, solvents, etc. More specifically, the instant specification discloses that “the suppository” includes other ingredients such as various carriers at p. 13, lines 7+.

Thus, the transition phrase “consisting essentially of” is interpreted to be open language, not close language as asserted by applicant.

*Applicants also argue that the references only teach prophylactic treatment of, not treatment of migraine. (Reply, pp.9-10).*

First, prophylactic treatment reads on “treating a migraine headache” of the instant claim. The instant specification does not exclude “prophylactic treatment” from treatment. In fact, the instant specification recites “the present invention is useful for inhibiting or moderating a migraine headache, while also being able to be used to prevent the onset of a migraine headache attack” (spec. p.4, lines 29+). Thus, in light of the instant specification, “treating” a migraine headache includes “inhibiting” and “preventing” migraine.

Second, the cited reference (Sorensen) clearly teaches treatment of migraine using valproate. The reference teaches administering “valproate” to patients with migraine (see Abstract).

*Applicant also seems to argue that there is no motivation to combine the references. (Reply, p.9, para 2).*

Applicant is respectively directed to the previous Office action (mailed 10/2/06; pp.14-15) for discussion of motivation to combine.

Art Unit: 1639

Applicants are also respectively directed to the recent Supreme Court decision, which forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. *KSR, 127 S.Ct. at 1741, 82 USPQ2d at 1396.*

*Applicant also argues "the Murata, et al. patent does not disclose the suppository without the inclusion of additional compositions", and thus the reference's teaching does not read on the instant claim (Reply, p. 10, para 3).*

However, the instant claim (Claim 30) is not drawn to a suppository consisting only of valproate "without inclusion of additional compositions". Thus, the combination of the said references is obvious over the instant claimed invention.

#### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

#### **Murata**

12. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,500,221 (Murata et al; cited previously). The previous rejection is maintained for the reasons of record as set forth in the Office action, mailed 3/23/07, at p. 7+, as well as the discussion below.

Discussion and Answer to Argument

13. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

*Applicants assert the instant claim 22 have been amended to have "closed language and therefore does not read on the '221 patent". (Reply, p.11, para 2).*

As discussed supra under the rejection of Sorensen et al, the transition phrase "consisting essentially of" is not interpreted to be closed language.

Applicants are respectively directed to MPEP 2111.03 for guidance on interpretation of various transition phrases:

"The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original)..."

"A consisting essentially of" claim occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003)..."

"In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)"

Art Unit: 1639

(emphasis added).

In the instant case, applicant has not provided any evidence to indicate that the transition phrase “consisting essentially of” should be interpreted as closed language. The instant specification, on the other hand, do indicate that the phrase “consisting essentially of” should be interpreted to mean open language. That is the “additional components” would not materially change the characteristics of applicant’s invention, as according to the case law.

The instant specification does not disclose “a suppository” that “consist of” only valproate, sodium valproate, or valproate salts. The instant specification discloses “medication composition” that “includes” various chemical compounds such as the ones listed at p. 5, lines 12+. The instant specification also discloses that the “medication composition” would comprise other ingredients so that the medication composition can be in various forms such as liquid, gel, paste, suspension, etc., as disclosed at p. 5, lines 22. The instant specification also discloses that the medication composition can include other substances such as thickeners, pharmaceutical carriers, solvents, etc. More specifically, the instant specification discloses that “the suppository” includes other ingredients such as various carriers at p. 13, lines 7+.

Thus, the transition phrase “consisting essentially of” is interpreted to be open language, not close language as asserted by applicant.

The Murata reference teaches, for example, “A sustained-release suppository preparation, comprising a therapeutically effective amount of an acidic drug or a pharmaceutically acceptable salt thereof which can be absorbed by rectal administration and an acidic compound or a pH buffering agent mixed in a pharmaceutically acceptable base component, wherein said acidic drug or pharmaceutically acceptable salt thereof is selected from the group consisting of

Art Unit: 1639

sodium valproate" (see Claim 1 of the reference). Clearly, the reference teaches a suppository "consisting essentially of" valproate salts.

*New Claim Objections/Rejections*

*Claim Rejections - 35 USC § 112*

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the phrase "said medication being in a pharmaceutically acceptable carrier" in line 4, which is unclear. The said recitation is in conflict with the transition phrase "consisting of" in line 2 of the claim. Given broad and reasonable interpretations of the phrase "said medication being in a pharmaceutically acceptable carrier", the recitation seems to dictate that other materials (such as pharmaceutically acceptable carrier) are in addition to the medication. That is the claimed "medicine suppository" comprises both the "medication" and "pharmaceutical acceptable carrier". However, the instant claim 22 also recites "A medicine suppository ... consisting of ... a medication" in lines 1-2. That is the claimed "medicine suppository" can consist only of "a valproate compound" excluding any other elements. (see MPEP 2111.03 for interpretation of "consisting of"). Therefore, the said phrase "said medication being in a pharmaceutically acceptable carrier" in line 4 of the claim is in conflict with the

Art Unit: 1639

transition phrase "consisting of" in line 2 of the claim. One of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the instant claimed invention.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sue Liu/  
Patent Examiner, AU 1639  
10/19/07